



March 21, 2003

Jennifer K. Holmes, Ph.D.  
Patent Agent  
Boston Office  
617.832.1770  
jholmes@foleyhoag.com

Assistant Commissioner of Patents  
Washington, DC 20231

Re: U.S. Patent Application Serial No. 09/888,056  
Filed: June 22, 2001  
Entitled: *Screening Assays for Identifying Modulators of the Inflammatory  
Or Immune Response*  
Inventors: Kornman and Duff  
FH Reference No. MSA-023.01 (20974-2301)

Dear Sir:

Enclosed for filing in the above-referenced patent application, please find the following:

1. Response to Restriction Requirement;
2. Return Receipt Postcard.

The Commissioner is hereby authorized to charge any under-payments or credit any over-payments to our Deposit Account No. 06-1448.

Certificate of First Class Mailing	
<p>I hereby certify that this correspondence is being deposited with the U.S. Postal Service with sufficient postage as First Class Mail in a box addressed to: Commissioner for Patents, Washington, DC 20231 on the date set forth below:</p>	<p>Respectfully submitted, FOLEY, HOAG LLP</p> <p><i>Jennifer K. Holmes</i> Jennifer K. Holmes, Ph.D. Reg. No. 46,778 Agent for Applicants Customer ID No. 25181</p>
<p><u>March 21, 2003</u> Date</p>	<p><i>Kristen Willett</i> Kristen Willett</p>



**IN THE UNITED STATES PATENT AND TRADEMARK OFFICE**

Applicants: Kornman & Duff	Atty. Docket No.: <u>MSA-023.01</u>
Serial No.: 09/888,056	Examiner: A. Chakrabarti
Filing Date: June 22, 2001	Art Unit: 1634
Title: <i>Screening Assays for Identifying Modulators of the Inflammatory or Immune Responses</i>	

**Certificate of First Class Mailing**

I hereby certify that the instant "*Response to Restriction Requirement*" is being deposited on the date set forth below with the U.S. Postal Service as First Class Mail in an envelope addressed to: Commissioner for Patents, Washington, D.C. 20231.

March 21, 2003  
Date of Signature and Mail Deposit

By: Kristen Willett  
Kristen Willett

Commissioner for Patents  
Washington, DC 20231

**RESPONSE TO RESTRICTION REQUIREMENT**

Dear Sir:

In response to the outstanding Restriction Requirement of February 21, 2003, Applicants provisionally elect, with traverse, Group I, claims 1-27. However, it is respectfully submitted that examination of all claims simultaneously would place no undue burden on the Examiner. The Applicants respectfully point out that examination of the claims of Group II (claims 28-34) and the claims for Group III (claims 35-37) necessarily entail a search of the subject matter of Group I, and therefore submit that the examination of Groups I, II and III together present no significant burden over the examination of Group I alone.

For a restriction requirement to be valid, the Examiner must establish that the search and examination of the entire application cannot be made without serious burden (M.P.E.P § 803). Accordingly, Applicants respectfully request examination of all claims simultaneously.

### Species Election

The Examiner has further required the election of a species for Group I claims 1-27 as the Examiner contends that “(c)laims 4, 6, 19, and 21 are generic to a plurality of disclosed patentably distinct species comprising 21 structurally different alleles”, “(c)laims 5 and 20 are generic to a plurality of disclosed patentably distinct species comprising 27 different diseases”, “(c)laim 7 is generic to a plurality of disclosed patentably distinct species comprising 7 structurally different biomarkers”, “(c)laim 22 is generic to a plurality of disclosed patentably distinct species comprising 6 structurally different biomarkers” and “(c)laim 27 is generic to a plurality of disclosed patentably distinct species comprising 11 structurally different inducers”.

In response, Applicants hereby provisionally elect with traverse to have claims 4, 6, 19 and 21 examined with respect to allele 1 of IL-1A(+4845). Applicants also provisionally elect with traverse to have claims 5 and 20 examined with respect to coronary artery disease. Applicants provisionally elect with traverse to have claim 7 examined with respect to blood or urine IL-1 $\alpha$  levels. Applicants further provisionally elect with traverse to have claim 22 examined with respect to IL-1 $\alpha$  production. Applicants also provisionally elect with traverse to have claim 27 examined with respect to interleukin-1.

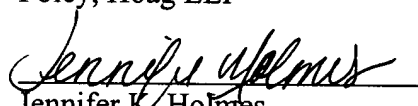
Applicants traverse the several requirements for election because claims so restricted would not recite mutually exclusive characteristics and the various embodiments of the invention are not mutually exclusive. As described in M.P.E.P. § 806.04(f), claims drawn to different species must recite the mutually exclusive characteristics of such species. Applicants point out that the species identified in the Office Action are not necessarily mutually exclusive, so that the claims cannot be restricted to mutually exclusive species. For example, a test subject, as set forth in claims 1 and 16 and the claims dependent thereto, may have more than one of the alleles recited in claims 4 and 19. Similarly, a subject may have more than one of the predispositions set forth in claim 5 and 20. Furthermore, more than one biomarker may be observed within a subject. With reference to claim 16 and its dependent claims, more than one inducer can be administered to cells obtained from a test subject or cells propagated therefrom. Similarly more than one of the biomarkers may be observed in cells obtained from a test subject or cells propagated therefrom. Thus, a claim restricted to, for example, a single allele species, would not

necessarily be mutually exclusive to a claim restricted to another allele species. Therefore, a claim restricted in the manner suggested by the Examiner would recite a feature that could be found in more than one species. Applicants accordingly request that the requested species elections as to allele, as to disposition, as to biomarker, and as to inducer be reconsidered and withdrawn.

Applicants emphasize that they are not addressing the patentable distinctiveness of any species. As described in M.P.E.P. § 806.04(h), patentable distinctiveness of species is an issue separate from mutual exclusivity. Applicants' assertion regarding the absence of mutual exclusivity among the identified characteristics does not admit or imply that disclosed species are unpatentable over one another. In conclusion, Applicants request consideration and withdrawal of the present election requirement in view of these arguments.

Any questions raised by this submission may be directed to the undersigned at (617) 832-1000. The Commissioner is hereby authorized to charge any underpayments, or credit any overpayments, to our **Deposit Account No. 06-1448**.

**Customer No. 25181**  
155 Seaport Boulevard  
Boston, MA 02210  
Tel: (617) 832-1000  
Fax: (617) 832-7000  
Date: March 21, 2003

Respectfully submitted,  
Foley, Hoag LLP  
By:   
Jennifer K. Holmes  
Reg. No. 46,778  
Agent for Applicants